

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of: AMMANN, Christina et al. Confirmation No.: 8957

Application No.: 10/564,452

Group Art Unit: 1781

Filing Date: January 12, 2006

Examiner: GWARTNEY, Elizabeth A.

For: HIGH FIBRE HIGH CALORIE
LIQUID OR POWDERED NUTRITIONAL
COMPOSITION

Attorney Docket No. 7444-US-PCT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S REPLY BRIEF

Sir:

I. INTRODUCTION

Appellant submits Appellant's Reply Brief in response to the Examiner's Answer dated July 8, 2010 pursuant to 37 C.F.R. § 41.41(a). Appellant respectfully submits that the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated December 1, 2009 as noted in Appellant's Appeal Brief filed on April 22, 2010, for at least the reasons set forth below. Accordingly, Appellant respectfully requests that the rejections of pending Claims 1-2 and 8-15 be reversed.

II. THE REJECTION OF CLAIMS 1-2 AND 8-15 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE, EVEN IF THE EXAMINER ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS, APPELLANT HAS REBUTTED THE *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellant respectfully requests that the Board reverse the rejections of Claims 1-2 and 8-15 under 35 U.S.C. §103(a) because the *Declaration* submitted on January 20, 2010 demonstrates secondary considerations that overcome the obviousness rejection. In addition, the cited references fail to disclose each and every element of the present claims.

In the Examiner's Answer, the Examiner states that "[w]hether evidence shows unexpected results is a question of fact and the party asserting unexpected results has the burden of proving that the results are unexpected." See, Examiner's Answer, page 15, lines 3-4. The Examiner further states that "the increased fiber supplement (Clinutren[®] 1.5 Fiber) of Exhibit 1 has not been shown to be commensurate in scope with the rejected to claims." See, Examiner's Answer, page 15, lines 17-18. The Examiner also states that "Appellant[] ha[s] not shown that the comparison from the study summarized in Exhibit 1 represents the closest prior art." See, Examiner's Answer, page 16, lines 1-2. Appellant respectfully disagrees and submits that Appellant has sufficiently demonstrated secondary considerations that overcome the obviousness rejection.

With respect to the Examiner's statement that "the increased fiber supplement (Clinutren[®] 1.5 Fiber) of Exhibit 1 has not been shown to be commensurate in scope with the rejected to claims," Appellant submits that MPEP §716.02(d) explicitly states that the nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. See, MPEP §716.02(d). With respect to the present claims, Appellant respectfully submits that, even if the claims are slightly broader than the data summarized in the *Declaration*, the MPEP expressly states that such results can still rebut a finding of obviousness.

As discussed in the previously submitted *Declaration*, in the summary of Exhibit 1 of the *Declaration*, there were no reported negative effects of either of the oral supplements Clinutren[®] 1.5 or Clinutren[®] 1.5 Fiber. In particular, the increased fiber supplement (Clinutren[®] 1.5 Fiber), which includes a similar fiber content, including pea outer fiber, to the presently claimed

compositions, did not promote any undesired abdominal symptoms. Accordingly, the increased fiber supplement (Clinutren[®] 1.5 Fiber) was surprisingly as well tolerated as a similar, non-fiber composition (Clinutren[®] 1.5). Thus, even if the “the increased fiber supplement (Clinutren[®] 1.5 Fiber) of Exhibit 1” is claimed slightly broader than the testing data in Exhibit 1 demonstrates, Appellant submits that this is not dispositive of the surprising and unexpected results achieved through administration of the increased amount of fiber and that such a demonstration is perfectly acceptable under MPEP §716.02(d).

Regarding the Examiner’s statement that “Appellant[] ha[s] not shown that the comparison from the study summarized in Exhibit 1 represents the closest prior art,” Appellant maintains that a comparison between the present claims and *Spivey-Krobath* (the “closest prior art,” according to the Examiner) is not as good of a comparison as the comparison outlined in the Exhibits of the previously submitted *Declaration*. As shown in as Exhibits 2 and 3 of the *Declaration*, Clinutren[®] 1.5 Fibre and Clinutren[®] 1.5 are similar compositions that differ with respect to the fiber content. The studies performed by Appellant indicate that increased fiber supplement (Clinutren[®] 1.5 Fiber), which includes a similar fiber content, including pea outer fiber, to the presently claimed compositions, did not promote any undesired abdominal symptoms. Accordingly, the increased fiber supplement (Clinutren[®] 1.5 Fiber) was surprisingly as well tolerated as a similar, non-fiber composition (Clinutren[®] 1.5).

Therefore, the comparison between Clinutren[®] 1.5 Fibre, which includes a similar fiber content, including pea outer fiber, to the presently claimed compositions, and Clinutren[®] 1.5 is an even better comparison than the present claims and *Spivey-Krobath*, which fails to disclose or suggest each and every element of the present claims including, for example, protein content, the source of dietary fiber, and the composition viscosity. Accordingly, Appellant submits that a comparison of the present claims and *Spivey-Krobath* would be less informative than the comparison between Clinutren[®] 1.5 Fibre and Clinutren[®] 1.5 presented by Appellant.

In the Examiner’s Answer, the Examiner maintains that “*Brassart* et al. teach a fiber containing nutritional composition including soluble and insoluble fiber, i.e. pea outer fiber” and that “*Spivey-Krobath* . . . disclose[s] a nutritional composition comprising dietary fiber wherein the source of dietary fiber is a combination of fructooligosaccharides and acacia gum.” See, Examiner’s Answer, page 16, lines 15-21. However, Appellant respectfully submits that even if *Brassart* discloses one component of the presently claimed dietary fiber blend, and *Spivey-*

Krobath discloses two components of the presently claimed dietary fiber blend, this is not enough to render the present claims obvious because of the demonstration of surprising and unexpected results in the *Declaration*. Indeed, not only do the present claims require a blend of all three components, but the present claims require specific amounts of the components. Appellant respectfully submits that the skilled artisan would not have expected such a synergistic result from the combination of all three components simply by reviewing the *Brassart* and *Spivey-Krobath* references.

Further, as admitted by the Examiner, *Spivey-Krobath* and *Brassart* fail to disclose or suggest each and every element of the present claims because *Spivey-Krobath* and *Brassart* fail to disclose or suggest a nutritional composition comprising 4.5 to 6g protein/100ml composition as required by independent Claims 1 and 10-15. *Spivey-Krobath* and *Brassart*, alone or in combination, also fail to disclose or suggest a source of dietary fiber comprising a specific blend of 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligosaccharides. Finally, *Spivey-Krobath* and *Brassart*, alone or in combination, fail to disclose or suggest that the nutritional composition comprises a viscosity of 30 – 80 mPas as required by independent Claims 1 and 10-15.

Instead, and as discussed in detail in the Appeal Brief, the only reference to specific amounts of protein at any place in *Spivey-Krobath* is in Table 1 on page 10 where it is specified that the composition contains either 10.5 or 7.0 g protein/100ml of composition dependent on the desired energy content of the composition, which falls outside the claimed range. See, *Spivey-Krobath*, Table 1 (emphasis added). Further, the only place in the disclosure of *Brassart* that discusses specific amounts of protein are in the examples, where 3.8g protein/100ml composition was used, which is below the claimed range. See, e.g., *Brassart*, Example 1 (emphasis added). Accordingly, for at least this reason, it is clear that the cited references fail to disclose or suggest each and every element of the present claims.

For at least the reasons set forth above, Appellant submits that, even if the Examiner has made out a prima facie case of obviousness, which Appellant submits is not the case, Appellant has “rebut[ted the] prima facie case of obviousness [by making] a showing of ‘unexpected results,’ i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.” *In*

